

**Notice of Allowability**

Application No.

09/743,825

Applicant(s)

CHAQUI ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to interview of 05/08/06.
2. ☒ The allowed claim(s) is/are 2-3, 5, 10, 12, 17, 19, 27-31, 33, renumbered as 1-13.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☒ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 05/08/06.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other PTO-90

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with NANCY AXELROD on 05/08/06 and 05/16/06.

The application has been amended as follows:

In the specification:

1) The following continuation data was inserted to the first line after the title, on page 1 of the specification:

#### RELATED APPLICATIONS

This application is a 371 national stage Application of PCT/US99/16831, filed on 07/23/1999, which claims benefit of Application Serial Number 60/094,137, filed on 07/24/1998, now abandoned.

2) The specification was amended as follows:

In the specification, page 5, line 28<sup>th</sup>, after the first "transcript" word ---- (SEQ ID NO:1 and SEQ ID NO:2, respectively) --- was inserted.

In the specification, page 5, line 28<sup>th</sup>, after "the 5 kb transcript" --- (SEQ ID NO:3 and SEQ ID NO:4, respectively) --- was inserted.

In the claims:

Claims 1, 4, 6-9, 11, 13-16, 18, 20-26, 32, 34-40 were cancelled.

Claim 19 was amended as follows: "from a primary prostate tumor" was deleted, and --- of a tissue from a primary prostate cancer --- was inserted.

Claim 30 was amended as follows: "from a primary prostate tumor" was deleted, and --- of a tissue from a primary prostate cancer --- was inserted.

2. The amendment of claims 19, 30 is supported on page 3, last paragraph, and page 13, example 1. The amendment obviates the 112, first paragraph, new matter issue for the language "a sample from a primary prostate tumor".

3. The request of 11/09/04 and 05/26/06 to correct inventorship, by adding Michael R. Emmert-Buck as an inventor is granted and entered (see the enclosed PTO-90).

4. The following is an Examiner's statement of reasons for allowance:

The claimed nucleic acid and method of detecting prostate cancer is novel. The closest prior art for SEQ ID NO:1 is the cDNA SEQ ID NO:21(HP10302) of 2373 nucleotides in length from a liver cDNA library, as taught by Kato et al (WO 98/21328-A2, p. 56-57, of record), which is only 99.5% similar to SEQ ID NO:1 of 2326 nucleotides in length of the instant application, from nucleotide 64 to nucleotide 2317 of SEQ ID NO:1 of the instant application (see the Office action of 05/05/04, on pages 19-20). Moreover, Kato et al do not teach or suggest that SEQ ID NO:21 is overexpressed in prostate cancer, nor a method for detecting prostate cancer, using SEQ ID NO:21. The closest prior for SEQ ID NO:7 is a 20 nucleotide primer, taught by Kachiku (JP08154685-A, published on 06/18/1996), which is only 58% similar to SEQ ID NO:7 (see MPSRCH search report, 2006, us-09-743825-7.rng, pages 7-8). The closest prior for SEQ ID NO: 8 is a 20 nucleotide primer, taught by Buell et al (US 6,509,163-B1), which is only 61% similar to SEQ ID NO:8 (see MPSRCH search report, 2006, us-09-743825-8.rng, page

Art Unit: 1642

4). The closest prior for SEQ ID NO:10 is a 20 nucleotide primer, taught by Feder et al (US 6,849,399-B1), which is only 63% similar to SEQ ID NO:10 (see MPSRCH search report, 2006, us-09-743825-10.rng, page 4).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS  
May 31, 2006

  
JEFFREY SIEW  
SUPERVISORY PATENT EXAMINER

Application/Control Number: 09/743,825  
Art Unit: 1642

Page 5

**UNITED STATES DEPARTMENT OF COMMERCE****U.S. Patent and Trademark Office**

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER
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20060512

DATE MAILED:

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner for Patents**

The request of 11/09/04 and 05/26/06 to correct inventorship, by adding Michael R. Emmert-Buck as an inventor, in addition to the existing inventors Rodrigo F. Chaqui, Kristina A. Cole, and Lance A. Liotta is granted and entered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

May 31, 2006

**VENABLE** LLP575 7th Street, NW  
Washington, DC 20004-1601Telephone 202-344-4000  
Facsimile 202-344-8300

www.venable.com

## TO:

Examiner Minh-Tam Davis  
U.S. PTO

## FAX NUMBER:

(571) 273-0830

## PHONE NUMBER:

## SENDER:

Nancy J. Axelrod

## SENDER'S FAX NUMBER:

202-344-8300

## SENDER'S PHONE NUMBER:

202-344-8334

## SENDER'S ASSISTANT:

Lili Froehling

## ASSISTANT'S PHONE NUMBER:

202-344-4284

## DATE:

5/16/2006

## CLIENT/MATTER NUMBER:

31978-202420

## PAGES, EXCLUDING COVER:

9

## MESSAGE:

**Re: S/N 09/743,825**

Dear Tam,

In accordance with your telephonic request today, enclosed is another copy of the paper we filed in the above-referenced application on June 9, 2005. This paper provides copies of references that had been cited by the Examiner, and that had apparently been lost by the PTO.

With best regards,

Nancy Axelrod, Ph.D.

Patent Agent

VENABLE LLP

575 7th Street, N.W.

Washington, DC 20004-1601

202-344-8334 direct

202-344-4000 main

202-344-8300 fax

<http://www.venable.com><mailto:njaxelrod@venable.com>

If you require assistance with this transmission, please contact the sender.

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**127005**

Venable Filing Number

Attorney/LAA: NJA/rahs  
 PTO Due Date: \_\_\_\_\_  
 Date Filed: June 9, 2005

TM Official  
 Gazette Date: \_\_\_\_\_

Atty. Docket No: 31978-202420  
 Re: "PB39, A GENE DYSREGULATED IN PROSTATE CANCER, AND USES THEREOF"  
R. CHUAQUI et al.  
 Application No: 09/743,825  
 Patent No.: \_\_\_\_\_

Appl'n Filing Date: JANUARY 15, 2002  
 Issue Date: \_\_\_\_\_

The following items were received from Venable, Washington, D.C., by the U.S. Patent & Trademark Office:

**U.S. PTO FEES ENCLOSED**

- ☐ Transmittal Form (PTO/SB/21)  
☐ Fee Transmittal Letter  
☐ New U.S. Utility Application ( \_\_\_\_\_ pages of specification/claims)  
☐ Submission Of Formal Drawing (Sheets - Figs.)  
☐ Invention Declaration  
☐ U.S. National Stage Application of PCT Application  
☐ Translation of International Application  
☐ New U.S. TM Application ( \_\_\_\_\_ specimens)  
☐ Rule 53(d) Continued Prosecution Application  
☐ Substitute Specification  
☐ Rule 53(b) Continuation or Divisional Application (*attach copy of specification, claims, drawings & declaration*)  
☐ Priority Document-Cert. Copy of Appln.#: \_\_\_\_\_ ; Country \_\_\_\_\_  
☐ Date Filed: \_\_\_\_\_  
☐ Request for Continued Examination (RCE) under 37 CFR 1.114  
☐ Request for Reconsideration  
☐ Application Data Sheet  
☐ Assignment w/Cover Sheet  
☐ IDS w/ PTO/SB/08A  
☐ Status Inquiry  
☒ **RESPONSE TO NOTICE UNDER 37 C.F.R. 1.251**  
☒ **COPY NOTICE UNDER 37 C.F.R. 1.251 w/ REFERENCE**  
☐ Notice of Appeal  
☐ Appeal Brief (*in triplicate*)  
☐ ☐ Reply Brief (*in triplicate*) / ☐ Request for Oral Hearing  
☐ Confirmation of Hearing Petition  
☐ Issue Fee Transmittal  
☐ Certificate of Correction  
☐ Maintenance Fee Transmittal  
☐ Power of Attorney  
☐ Response to Notice to File Missing Parts  
☐ Response to Notice to File Missing Requirements  
☐ Response to Restriction Requirement  
☐ Petition to Revive  
☐ Sequence Listing - CDR Enclosed? ☐ Yes ☐ No  
☐ Request for Non-Publication  
☐ Request to Rescind Non-Publication Request  
☐ Terminal Disclaimer  
☐ Notice of Opposition (*Please list all documents in Other section*)  
☐ Amendment to Alleged Use

\_\_\_\_\_ Filing Fee  
 \_\_\_\_\_ Surcharge Fee  
 \_\_\_\_\_ Additional Claim Fee  
 \_\_\_\_\_ Multiple Dependent Claim Fee  
 \_\_\_\_\_ IDS Fee  
 \_\_\_\_\_ Extension Fee  
 \_\_\_\_\_ Notice of Appeal Fee  
 \_\_\_\_\_ Brief on Appeal Fee  
 \_\_\_\_\_ Oral Hearing Request Fee  
 \_\_\_\_\_ Petition Fee  
 \_\_\_\_\_ Issue Fee  
 \_\_\_\_\_ Publication Fee  
 \_\_\_\_\_ Maintenance Fee  
 \_\_\_\_\_ TM Statement of Use  
 \_\_\_\_\_ 8 Affidavit Fee  
 \_\_\_\_\_ 8 and 15 Affidavit  
 \_\_\_\_\_ TM Renewal Application Fee  
 \_\_\_\_\_ TM Extension of Time Fee

-NONE- Total Fees Paid

☐ Check Number \_\_\_\_\_ Attached  
☐ Charge Any Fees Due to Deposit Account  
 22-0261\*  
☐ Yes ☐ No

\*If the Deposit Account was used, was a copy of this form sent to Accounting?

::ODMA\PCDOCS\DC2DOCS\1655795\1



PATENT  
Attorney Docket No.: 31978-202420**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**In re application of: R. Chuaqui *et al.*

: Examiner: Minh-Tam DAVIS

Serial No.: 09/743,825

: Group Art Unit: 1642

Filed: January 15, 2002

: USPTO Customer No.: **45323**For: PB39, A GENE DYSREGULATED IN  
PROSTATE CANCER, AND USES  
THEREOF


: Confirmation No. 8611

**RESPONSE TO NOTICE UNDER 37 C.F.R. 1.251**Assistant Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA. 22313-1450**ATTENTION: MAIL STOP AF**

Sir:

In response to the Notice Under 37 C.F.R. 1.251, applicant have provided copies of the last two references from the "List of References Cited by Examiner (PTO-892), dated May 5, 2004. The copy of each paper is a complete and accurate copy of applicant's record of such paper.

Respectfully submitted,

Date: June 9, 2005  
Nancy J. Axelrod, Ph.D.  
Registration No. 44,014  
VENABLE LLP  
575 7<sup>th</sup> Street, NW  
Washington, D.C. 20004-1601  
Direct telephone: (202) 344-8334  
Telefax: (202) 344-8300

::ODMA\PCDOCS\DC2DOCS\1654471\1

**UNITED STATES PATENT AND TRADEMARK OFFICE**

COMMISSIONER FOR PATENTS

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**NOTICE UNDER 37 CFR 1.251 - Pending Application**

☐ The file on the cover sheet cannot be located after a reasonable search. Therefore, the Office is initiating the reconstruction of the file of the above-identified application pursuant to the provisions of 37 CFR 1.251.

Applicant is hereby requested to provide a copy of applicant's record (if any) of all of the correspondence between the Office and applicant for the above-identified application (except for U.S. patent documents), a list of such correspondence, and a statement that the copy is a complete and accurate copy of applicant's record of all of the correspondence between the Office and the applicant for the above-identified application (except for U.S. patent documents), and whether applicant is aware of any correspondence between the Office and applicant for the above-identified application that is not among applicant's records.

☒ The following paper(s) pertaining to the above-identified application cannot be located after a reasonable search:

The last two references from the "List of References Cited by Examiner (PTO-892)," dated 5/5/04:

- MPSRCH sequence search report, 2004, us-09-743-825-1.mg, pages 4-6
- Genbank Sequence Database, Accession No: G22380, and MPSRCH search report, 2004, us-09-743-825-7.rge, p. 1-2, and us-09-743-825-10.rge, p. 1-2

Therefore, the Office is initiating the reconstruction of such paper(s) pursuant to the provisions of 37 CFR 1.251.

Applicant is hereby requested to provide a copy of the paper(s) listed above and a statement that the copy of such paper(s) is a complete and accurate copy of applicant's record of such paper(s).

If applicant does not possess any record of the correspondence between the Office and the applicant for the file listed on the cover sheet or any copy of the paper(s) listed, applicant must reply to this notice by providing a statement that applicant does not possess any record of the correspondence between the Office and the applicant for the above-identified application.

☐ A printout from PALM of the contents of the file of the above-identified application is included with this notice.

Direct the reply to this notice to:

U. S. Patent and Trademark Office  
Mail Stop: Duplicates  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Direct questions concerning this notice to:

Image Assistance Center/ Customer Service

1-(888)-786-0101

PTO Doc. Code: R251.NTC (Rev. 03/05)

## COMMISSIONER FOR PATENTS

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

In re Application of: RODRIGO F. CHAQUI et al.  
Application No.: 09/743825  
Filing Date: 01/15/2002  
Title: PB 39, A GENE DYSREGULATED IN PROSTATE CANCER,  
AND USES THEREOF  
Direct to: U. S. Patent and Trademark Office  
Mail Stop: Duplicates  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

## NOTICE UNDER 37 CFR 1.251 -- Pending Application

Statement (check the appropriate box):

☐ The copy submitted with this reply is a complete and accurate copy of applicant's record of all of the correspondence between the Office and the applicant for the above-identified application (except for U.S. patent documents), and applicant is not aware of any correspondence between the Office and applicant for the above-identified application that is not among applicant's records.

☐ The copy of the paper(s) listed in the notice under 37 CFR 1.251 is/are a complete and accurate copy of applicant's record of such paper(s).

☐ The papers produced by applicant are applicant's complete record of all of the correspondence between the Office and the applicant for the above-identified application (except for U.S. patent documents), and applicant is not aware of any correspondence between the Office and the applicant for the above-identified application that is not among applicant's records.

☐ Applicant does not possess any record of the correspondence between the Office and the applicant for the above identified application.

June 9, 2005  
Date

Nancy Axelrod  
Signature

Nancy J. Axelrod, Reg. No. 44,014  
Typed or printed name

A Copy of this notice should be returned with the reply.

Burden Hour Statement: This collection of information is required by 37 CFR 1.251. The information is used by the public to reply to a request for copies of correspondence between the applicant and the USPTO in order to reconstruct an application file. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This form is estimated to take 60 minutes to complete. This time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

PTO Doc Code: R251.RES (Rev. 03/05)

P.O. Box 1450, Alexandria, Virginia 22313-1450 - www.USPTO.GOV





**Page 6**

[illegible]

## NCBI Sequence Viewer



Nucleotide

Entrez	PubMed	Nucleotide	Protein	Genome	Structure	PMC	Taxonomy	Books	
Search		Nucleotide	for		Go		Clear		
Limits		Preview/Index		History		Clipboard		Details	
Display		default	Show		20	Send to		File	Get Subsequence
								Features	

1: G22380. human STS WI-1700...[gi:1342706]

LOCUS G22380 321 bp DNA linear STS 31-MAY-1996  
 DEFINITION human STS WI-17004, sequence tagged site.  
 ACCESSION G22380  
 VERSION G22380.1 GI:1342706  
 KEYWORDS STS; STS sequence; primer; sequence tagged site.  
 SOURCE Homo sapiens (human)  
 ORGANISM Homo sapiens

Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;  
 Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.

REFERENCE 1 (bases 1 to 321)

AUTHORS Hudson,T.

TITLE Whitehead Institute/MIT Center for Genome Research; Physically

Mapped STSs

JOURNAL Unpublished (1995)

## COMMENT

Contact: Thomas Hudson  
 Whitehead Institute/MIT Center for Genome Research  
 Whitehead Institute for Biomedical Research  
 9 Cambridge Center, Cambridge MA 02142 USA  
 Tel: 617 252 1900  
 Fax: 617 252 1902  
 Email: thudson@genome.wi.mit.edu

Primer A: TTTATAAATCTACGGCCATGGC

Primer B: CTGGATGACAGGCAATCAAG

STS size: 101

## PCR Profile:

Presoak:

Denaturation:

Annealing: 56 degrees C

Polymerization:

PCR Cycles: 35

Thermal Cycler:

## Protocol:

Template: 10 ng

Primer: each 5 pM

dNTPs: each 4 nM

Taq Polymerase: 0.025 units/ul

Total Vol: 20 ul

## Buffer:

MgCl2: 1.5 mM

KCl: 50 mM

Tris-HCL: 10 mM

pH: 9.3

Derived from dbEST (genbank accession R00504).

## FEATURES

source

Location/Qualifiers

1..321

ance Viewer

/organism="Homo sapiens"  
/mol\_type="genomic DNA"  
/db\_xref="taxon:9606"  
/map="291.1 cR from top of Chr11 linkage group"

35..135

35..56

complement(116..135)

STSprimer bindprimer bind

IGIN

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1 tncagtcttt acaaaaatag aacttctctt ggtatttata aatctacggc catggctcta
61 tgtgcatggt acaggtagaa aagccatatt gggcactcct tttggttgct caggccttga
121 ttgectgtca tccagggccc ttggtctgag aagtctatgc ggtcacctca gagccgctaa
181 gcacottcag tgggcccata ccattggcgg cgtactcctg ctggagccgg gcacggtaat
241 agaagaggta gggaaggcaa caggaatccc aggggagtga ggaatagcag gaggccccag
301 atttcacctt tagggggcaa g
```

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